§ 864.9320 Copper sulfate solution for specific gravity determinations.

(a) *Identification.* A copper sulfate solution for specific gravity determinations is a device used to determine whether the hemoglobin content of a potential donor's blood meets the required level (12.5 grams per 100 milliliters of blood for women and 13.5 grams per 100 milliliters of blood for men).

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to § 864.9.

[45 FR 60647, Sept. 12, 1980, as amended at 65 FR 2310, Jan. 14, 2000]

§ 864.9400 Stabilized enzyme solution.

(a) *Identification.* A stabilized enzyme solution is a reagent intended for medical purposes that is used to enhance the reactivity of red blood cells with certain antibodies, including antibodies that are not detectable by other techniques. These enzyme solutions include papain, bromelin, ficin, and trypsin.

(b) *Classification.* Class II (performance standards).

[45 FR 60647, Sept. 12, 1980]

§ 864.9550 Lectins and protectins.

(a) *Identification.* Lectins and protectins are proteins derived from plants and lower animals that cause cell agglutination in the presence of certain antigens. These substances are used to detect blood group antigens for in vitro diagnostic purposes.

(b) *Classification.* Class II (special controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to § 864.9.

[45 FR 60648, Sept. 12, 1980, as amended at 63 FR 59226, Nov. 3, 1998]

§ 864.9575 Environmental chamber for storage of platelet concentrate.

(a) *Identification.* An environmental chamber for storage of platelet concentrate is a device used to hold platelet-rich plasma within a preselected temperature range.

(b) *Classification.* Class II (special controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to § 864.9.

[45 FR 60648, Sept. 12, 1980, as amended at 63 FR 59226, Nov. 3, 1998]

§ 864.9600 Potentiating media for in vitro diagnostic use.

(a) *Identification.* Potentiating media for in vitro diagnostic use are media, such as bovine albumin, that are used to suspend red cells and to enhance cell reactions for antigen-antibody testing.

(b) *Classification.* Class II (special controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to § 864.9.

[45 FR 60649, Sept. 12, 1980, as amended at 63 FR 59226, Nov. 3, 1998]

§ 864.9650 Quality control kit for blood banking reagents.

(a) *Identification.* A quality control kit for blood banking reagents is a device that consists of sera, cells, buffers, and antibodies used to determine the specificity, potency, and reactivity of the cells and reagents used for blood banking.

(b) *Classification.* Class II (performance standards).

[45 FR 60649, Sept. 12, 1980]

§ 864.9700 Blood storage refrigerator and blood storage freezer.

(a) *Identification.* A blood storage refrigerator and a blood storage freezer are devices intended for medical purposes that are used to preserve blood and blood products by storing them at cold or freezing temperatures.

(b) *Classification.* Class II (special controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to § 864.9.

[45 FR 60650, Sept. 12, 1980, as amended at 63 FR 59226, Nov. 3, 1998]

§ 864.9750 Heat-sealing device.

(a) *Identification.* A heat-sealing device is a device intended for medical purposes that uses heat to seal plastic bags containing blood or blood components.

(b) *Classification.* Class I (general controls). The device is exempt from the

premarket notification procedures in subpart E of part 807 of this chapter subject to §864.9.

[45 FR 60650, Sept. 12, 1980, as amended at 65 FR 2311, Jan. 14, 2000]

§864.9875 Transfer set.

(a) *Identification.* A transfer set is a device intended for medical purposes that consists of a piece of tubing with suitable adaptors used to transfer blood or plasma from one container to another.

(b) *Classification.* Class II (performance standards).

[45 FR 60651, Sept. 12, 1980]

Subpart K—Products Used In Establishments That Manufacture Human Cells, Tissues, and Cellular and Tissue-Based Products (HCT/Ps)

§864.9900 Cord blood processing system and storage container.

(a) *Identification.* A cord blood processing system and storage container is a device intended for use in the processing and the storage of cord blood. This device is a functionally closed processing system that includes containers, other soft goods, and a centrifugation system for cord blood concentration, and a final container for the cryopreservation and the storage of a cord blood product.

(b) *Classification.* Class II (special controls). The special control for this device is FDA's guidance document entitled ''Class II Special Controls Guidance Document: Cord Blood Processing System and Storage Container.'' For the availability of this guidance document, see §864.1(d).

[72 FR 4638, Feb. 1, 2007]

PART 866—IMMUNOLOGY AND MICROBIOLOGY DEVICES

Subpart A—General Provisions

Sec.

866.1 Scope.
866.3 Effective dates of requirement for premarket approval.
866.9 Limitations of exemptions from section 510(k) of the Federal Food, Drug, and Cosmetic Act (the act).

Subpart B—Diagnostic Devices

866.1620 Antimicrobial susceptibility test disc.
866.1640 Antimicrobial susceptibility test powder.
866.1645 Fully automated short-term incubation cycle antimicrobial susceptibility system.
866.1700 Culture medium for antimicrobial susceptibility tests.

Subpart C—Microbiology Devices

866.2050 Staphylococcal typing bacteriophage.
866.2120 Anaerobic chamber.
866.2160 Coagulase plasma.
866.2170 Automated colony counter.
866.2180 Manual colony counter.
866.2300 Multipurpose culture medium.
866.2320 Differential culture medium.
866.2330 Enriched culture medium.
866.2350 Microbiological assay culture medium.
866.2360 Selective culture medium.
866.2390 Transport culture medium.
866.2410 Culture medium for pathogenic *Neisseria* spp.
866.2420 Oxidase screening test for gonorrhea.
866.2440 Automated medium dispensing and stacking device.
866.2450 Supplement for culture media.
866.2480 Quality control kit for culture media.
866.2500 Microtiter diluting and dispensing device.
866.2540 Microbiological incubator.
866.2560 Microbial growth monitor.
866.2580 Gas-generating device.
866.2600 Wood's fluorescent lamp.
866.2660 Microorganism differentiation and identification device.
866.2850 Automated zone reader.
866.2900 Microbiological specimen collection and transport device.

Subpart D—Serological Reagents

866.3010 *Acinetobacter calcoaceticus* serological reagents.
866.3020 Adenovirus serological reagents.
866.3035 *Arizona* spp. serological reagents.
866.3040 *Aspergillus* spp. serological reagents.
866.3050 Beta-glucan serological assays.
866.3060 *Blastomyces dermatitidis* serological reagents.
866.3065 *Bordetella* spp. serological reagents.
866.3085 *Brucella* spp. serological reagents.
866.3110 *Campylobacter fetus* serological reagents.
866.3120 Chlamydia serological reagents.
866.3125 *Citrobacter* spp. serological reagents.
866.3135 *Coccidioides immitis* serological reagents.
866.3140 *Corynebacterium* spp. serological reagents.